

## REMARKS

### A. Power of Attorney

Applicant has appointed the undersigned attorneys by and through the enclosed power of attorney.

### B. Restriction Requirement

The present application was subjected to a restriction requirement under 35 U.S.C. 121. Applicant hereby confirms the provisional election without traverse made by the attorney of record as set forth in the office action. Applicant has canceled the claims directed to the non-elected invention without prejudice or disclaimer for prosecution in a divisional application.

### C. Outstanding Action

Claims 1-23 were rejected under 35 U.S.C. 112.

Claims 1-23 were rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103 as stated in the outstanding office action.

Claims 24-38 have been withdrawn from consideration as being directed to a non-elected species.

### D. Status Of Claims

Claims 1-38 were pending in the application prior to the instant Amendment.

Claims 1-38 have been canceled without prejudice or disclaimer.

Claims 39-60 have been added and are now pending.

E. Amendments To The Specification

The specification is being review to correct any typographical errors and to insert terms in the specification found in the original disclosure of claims 5, 14 and 20 to providing proper antecedent basis for claims 5, 14 and 20.

The amendments to the specification will be filed under separate cover.

F. Claims

Applicant has canceled claim 1-38 and has introduced new claims 39-50 to more particularly point out and distinctly claim the subject matter of the invention. New claim 39-60 have been drafted to overcome the prior rejection under 35 U.S.C. 102, 35 U.S.C. 103 and 35 U.S.C. 112.

New independent claim 39 sets forth a sleep regulating pharmaceutical formulation for oral delivery before bedtime. The sleep regulating pharmaceutical formulation comprises a first component providing an initial prompt release of a sleep-compatible substance for effecting the onset of drowsiness and slumber. A second component contains at least one pharmaceutically wakeup agent. A third component delays the delivery of the wakeup agent of the second component for a period of time corresponding to a nominal interval of sleep.

None of the cited references either singularly or in combination suggest a sleep regulating pharmaceutical formulation having a first component having a sleep-compatible substance and a second component having a wakeup agent. The third component delays the delivery of the second component for a period of time after the first component.

None of the cited references either singularly or in combination suggest the use of a first component followed by a second component wherein the second component has an opposite pharmaceutical effect from the first component. The cited prior art is silent as to this novel feature of

the invention.

New independent claim 40 sets forth a sleep regulating pharmaceutical formulation for oral delivery before bedtime. The sleep regulating pharmaceutical formulation comprises an outer component providing an initial prompt release of a sleep-compatible substance for effecting the onset of drowsiness and slumber. An inner subsystem is located within the outer component comprising a core containing at least one wakeup agent. A coating encloses the core for delaying the delivery of the wakeup agent of the core for a period of time corresponding to a nominal interval of sleep.

None of the cited references either singularly or in combination suggest a sleep regulating pharmaceutical formulation having an outer component having a sleep-compatible substance and an inner subsystem is located within the outer component. The inner subsystem comprises a core containing a wakeup agent. The inner subsystem includes a coating completely envelopes the core for delaying, the delivery of the wakeup agent of the core for a period of time corresponding to a nominal interval of sleep.

It is respectfully submitted that the cited references either singularly or in combination do not teach or suggest such as sleep regulating pharmaceutical formulation.

New dependent claims 41-43 are dependent upon independent claim 40 further define the sleep-compatible substance set forth in independent claim 40.

New dependent claims 44-46 are dependent upon independent claim 40 further define the gas-generating substances set forth in independent claim 40.

New dependent claims 47-51 are dependent upon independent claim 40 further define the wakeup agent set forth in independent claim 40.

New dependent claims 52-58 are dependent upon independent claim 40 further define the semipermeable membrane set forth in independent claim 40.

New independent claim 59 sets forth a sleep regulating pharmaceutical formulation for oral delivery before bedtime. The sleep regulating pharmaceutical formulation comprises an outer component providing an initial prompt release of a sleep-compatible substance for effecting onset of drowsiness and slumber. An inner subsystem has a core containing an agglomeration of small wakeup agent subunits and gas-generating substances. The gas-generating substances generate gases upon reaction with water. A coating comprises an osmotic semipermeable membrane impermeable to the wakeup agent covering each of the agglomeration of small wakeup agent subunits and gas-generating substances. The osmotic semipermeable membrane is permeable to water for enabling water in the gastrointestinal tract to react with the gas-generating substance to progressively expand the osmotic semipermeable membrane in correlation with passage of time to delay the delivery of the agglomeration of small wakeup agent subunits for a period of time corresponding to a nominal interval of sleep.

It is respectfully submitted that the cited references either singularly or in combination do not teach or suggest such as sleep regulating pharmaceutical formulation.

New independent claim 60 sets forth a sleep pharmaceutical formulation for oral administration before bedtime. The sleep pharmaceutical formulation comprises a first component providing a neutral material having no pharmaceutical active material. A second component contains at least one pharmaceutical wakeup agent. A third component delays the delivery of the wakeup agent of the second component for a period of time corresponding to a nominal interval of sleep.

It is respectfully submitted that the cited references either singularly or in combination do not teach or suggest such as sleep regulating pharmaceutical formulation.

The prior art made of record but not relied upon has been reviewed and appears to be less

pertinent to the claimed subject matter than the references cited by the Examiner.

G. Request For Extension of Time

Enclosed is a Request for Extension of Time to respond to the outstanding office action.

H. Precautionary Request for an Extension of Time

In the event the present filing is not timely filed, applicant request an Extension of Time for an appropriate period of time. Please charge Deposit Account No. 06-2120 for the fees for any Extension of Time.

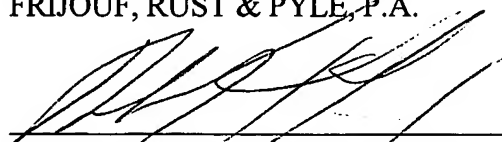
I. Additional Fees

Please charge Deposit Account No. 06-2120 for the fees for any additional claims, an Extension of Time, Citation of Prior Art, Petitions, Terminal Disclaimers or any other fee arising out of this correspondence.

Applicant verily believes that all claims are now in condition for allowance and favorable action is respectfully requested. The undersigned attorney of record cordially invites any telephonic communications from the examiner that may assist the examiner in the examination and to expedite the allowance and issuance of Letters Patent on the subject invention.

Respectfully submitted,

FRIJOUF, RUST & PYLE, P.A.



Robert F. Frijouf, Reg. No. 26,546  
201 East Davis Blvd Boulevard  
Tampa, Florida 33606  
813.254.5100 phone

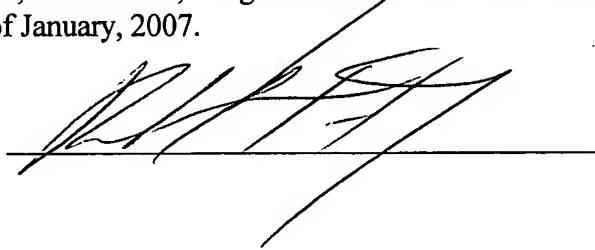
813.254.5400 facsimile  
[frijouf@frijouf.com](mailto:frijouf@frijouf.com) email  
Attorneys for Applicant

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Certificate of Mailing

It is hereby certified that the foregoing correspondence and fee is being placed in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450 and mailed by first class mail, postage prepaid, this 29<sup>th</sup> day of January, 2007.

A handwritten signature in black ink, appearing to be "D.H.F.", is written over a horizontal line.